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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0186]

Draft Guidance for Industry: Use of Material From Deer and Elk in Animal Feed; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#158) entitled "Use of Material From Deer and Elk in Animal Feed." This draft guidance document, when finalized, will describe FDA's current thinking regarding the use in animal feed of material from deer and elk that are positive for chronic wasting disease (CWD) or are at high risk for CWD.

DATES: Submit written or electronic comments on the draft guidance at any time, however, comments should be submitted by [*insert date 30 days after date of publication in the* **Federal Register**] to ensure their adequate consideration in preparation of the final document. FDA is requesting comments within 30 days, rather than within a longer period, because of the need to finalize the guidance in late August, prior to the start of the next deer hunting season.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your

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requests. Submit electronic comments on the draft guidance to http://www.fda.gov/dockets/ecomments. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, CVM (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0177, e-mail: bpritche@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CWD is a neurological (brain) disease of farmed and wild deer and elk that belong in the cervidae animal family (cervids). CWD belongs to a family of animal and human diseases called transmissible spongiform encephalopathies (TSEs). These include (1) Bovine spongiform encephalopathy (BSE or "mad cow" disease) in cattle; (2) scrapie in sheep and goats; and (3) classical and variant Creutzfeldt-Jakob diseases (CJD and vCJD) in humans. There is no known treatment for these diseases and there is no vaccine to prevent them. In addition, although validated postmortem diagnostic tests are available, there are no validated diagnostic tests for CWD that can be used to test for the disease in live animals.

Under FDA's BSE feed regulation (21 CFR 589.2000), most material from deer and elk is prohibited for use in feed for ruminant animals. This draft guidance document describes FDA's recommendations regarding the use in all

animal feed of all material from deer and elk that are positive for CWD or are considered at high risk for CWD.

The potential risks from CWD to humans or noncervid animals such as poultry or swine are not well understood. However, because of recent recognition that CWD is spreading rapidly in white-tailed deer and because CWD's route of transmission is poorly understood, FDA is making recommendations regarding the use in animal feed of rendered materials from deer and elk that are CWD positive or that are at high risk for CWD.

II. Significance of Guidance

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

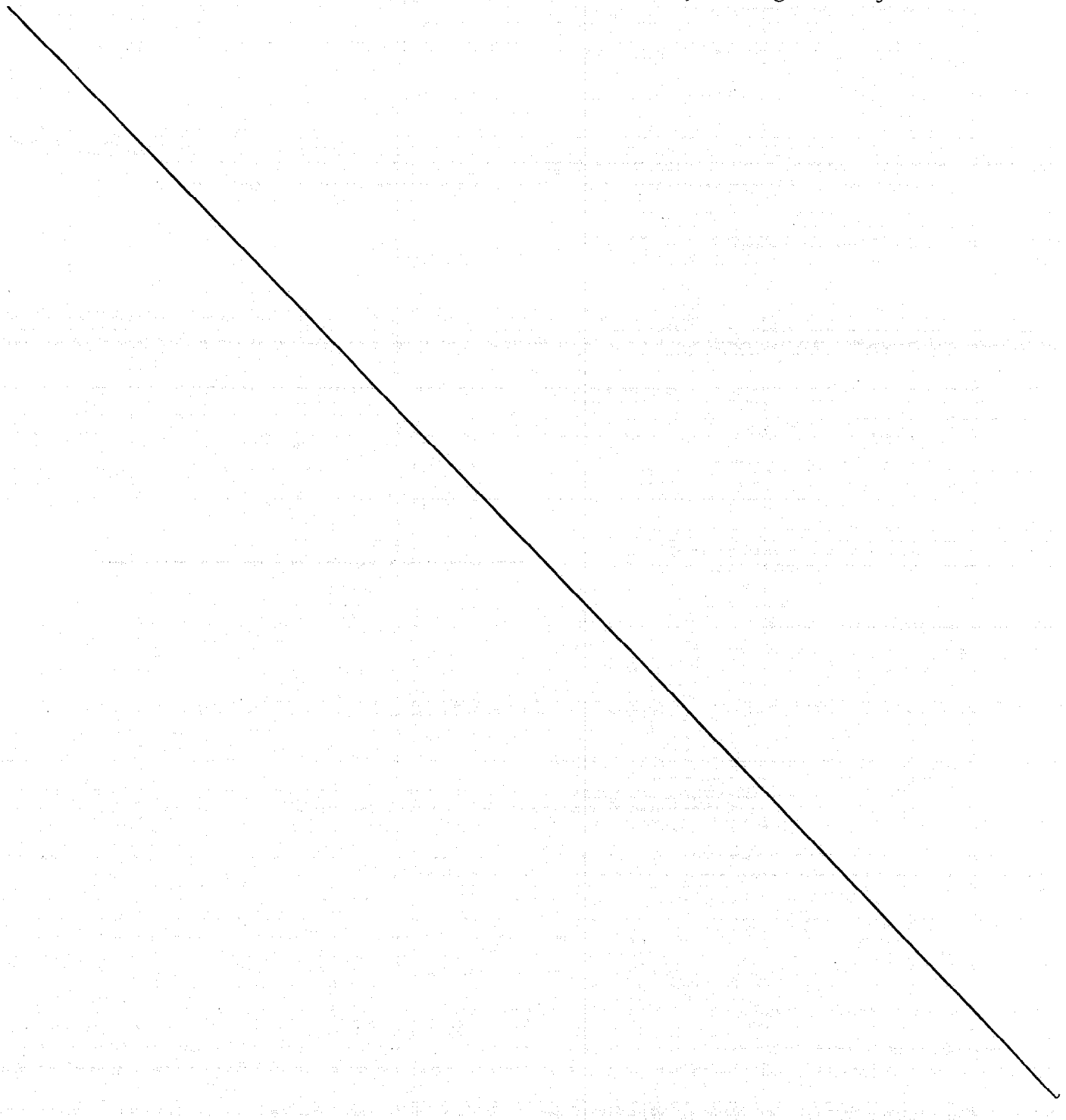
III. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Two paper copies of any

mailed comments are to be submitted, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



V. Electronic Access

Copies of the draft guidance document entitled "Use of Material From Deer and Elk in Animal Feed" may be obtained from the CVM home page (http://www.fda.gov/cvm) and from the Dockets Management Branch Web site (http://www.fda.gov/ohrms/dockets/default.htm).

Dated: 5/6/03
May 6, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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